

**TANGGUNG JAWAB HUKUM KOMISI ETIK PENELITIAN  
KESEHATAN (KEPK) DALAM PEMBERIAN PERSETUJUAN ETIK  
PENELITIAN DAN UJI KLINIK ALAT KESEHATAN**

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**ABSTRAK**

Penelitian ini bertujuan untuk mengetahui sinkronisasi pengaturan dan bentuk tanggung jawab hukum Komisi Etik Penelitian Kesehatan (KEPK) dalam pemberian persetujuan etik penelitian dan uji klinik alat kesehatan. Metode penelitian yang digunakan adalah yuridis normatif dengan metode pendekatan perundang-undangan, konseptual dan analitis. Spesifikasi penelitian yang digunakan meliputi inventarisasi peraturan perundang-undangan, sinkronisasi hukum, dan penemuan hukum *in concreto* dengan menggunakan metode analisis isi dan analisis perbandingan. Jenis data sekunder, metode pengumpulan data studi kepustakaan, metode pengolahan data Reduksi data, display data, dan klasifikasi data, metode penyajian data menggunakan teks naratif, metode analisis data normatif kualitatif, analisis isi, dan analisis komparatif. Hasil penelitian diperoleh bahwa pengaturan tanggung jawab hukum Komisi Etik Penelitian Kesehatan (KEPK) dalam pemberian persetujuan etik penelitian dan uji klinik alat kesehatan pada struktur peraturan perundang-undangan Indonesia telah menunjukkan taraf sinkronisasi. Artinya peraturan dengan derajat lebih rendah tidak bertentangan dan telah didasarkan pada peraturan dengan derajat yang lebih tinggi serta peraturan dengan derajat yang lebih tinggi menjadi pedoman bagi peraturan di bawahnya. Bentuk tanggung jawab hukum KEPK dalam pemberian persetujuan etik penelitian dan uji klinik kesehatan didasarkan pada Pasal 1365 dan 1366 KUH Perdata serta Pasal 359 dan 360 KUHP.

***Kata Kunci : Tanggung Jawab Hukum, Komisi Etik Penelitian Kesehatan  
(KEPK), Persetujuan Etik Penelitian, Uji Klinik Alat Kesehatan***

***THE HEALTH RESEARCH ETHICS COMMISSION (KEPK) LEGAL  
RESPONSIBILITY IN GIVING RESEARCH ETHICAL APPROVAL AND  
CLINICAL TESTING OF HEALTH EQUIPMENT***

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***ABSTRACT***

*The purpose of this research was to determine the synchronization of arrangements and forms of the health research ethics commission (KEPK) legal responsibility in giving research ethical approval and clinical testing of health equipment. The research method used is normative juridical with a statute approach, an analytical approach, and a conceptual approach. The research specifications are an inventory of laws and regulations, legal synchronization, and legal findings in concreto. Types of secondary data, library study data collection methods, data processing methods Data reduction, data display, and data classification, data presentation methods using narrative texts, qualitative normative data analysis methods, content analysis, and comparative analysis. Based on the research conducted, it was found that The regulation of The health research ethics commission (KEPK) legal responsibility in giving research ethical approval and clinical testing of health equipment has reached the level of synchronization. Decree of the Minister of Health of the Republic of Indonesia Number 1031/Menkes/SK/VII/2005 concerning National Guidelines for Health Research Ethics, Regulation of the Minister of Health No. 66 of 2013 concerning the Implementation of a Clinical Research Registry, Regulation of the Minister of Health of the Republic of Indonesia Number 63 of 2017 concerning Good Practices for Clinical Testing of Medical Devices, Government Regulation Number 39 of 1995 concerning Health Research and Development, Law Number 11 of 2019 concerning the National System of Science Knowledge and Technology and Law no. 36 of 2009 concerning Health, there are no provisions that regulate civil, criminal and administrative responsibility for the Health Research Ethics Commission in granting research ethics approval and clinical trials of medical devices. The responsibility of KEPK in granting ethical approval for health research and clinical trials is based on Articles 1365 and 1366 of the Civil Code and Articles 359 and 360 of the Criminal Code.*

***Keywords: Legal Responsibility, Health Research Ethics Commission (KEPK),  
Research Ethical Approval, Clinical Testing of Health Equipment***